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#### Declarations under Rule 4.17:

- as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for all designations
- as to the applicant's entitlement to claim the priority of the earlier application (Rule 4.17(iii)) for all designations

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### (54) Title: POLYHYDROXYALKANOATE NERVE REGENERATION DEVICES

(57) Abstract: Nerve regeneration devices are provided with improved rates of axonal regeneration, and methods for their manufacture are also disclosed. The devices are formed from a biocompatible, absorbable polymer, known as poly-4hydroxybutyrate. Growth factors, drugs, or cells that improve nerve regeneration may be incorporated into the devices. The devices are administered by implantation preferably without the use of sutures. In one aspect, the device is in the form of a wrap that can be used easily to capture the severed nerve bundle ends during surgery, and formed into a conduit in situ. If desired, the edges of the wrap can be melted together to seal the conduit, and hold it in place. A major advantage of the device is that it does not need to be removed after use since it is slowly degraded and cleared by the patient's body, yet remains functional in situ beyond the time required for nerve regeneration, and helps exclude scar tissue. The device also degrades in a cell-friendly manner, and does not release highly acidic or inflammatory metabolites. Furthermore, the device is flexible, strong, does not crush the regenerating nerve, is easy to handle, reduces surgical time by eliminating the need to harvest an autologous graft, and allows the surgeon to repair the nerve without a prolonged delay.

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